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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,510	09/29/2005	Karoly Tihanyi	23394	6075

535 7590 02/05/2008

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EXAMINER	
ROGERS, JUNE MARIE	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
02/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,510	TIHANYI ET AL.	
	Examiner	Art Unit	
	JUNE ROGERS	4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-5 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-5 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 9/29/2005.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Status of the claims

Claims 1-5 are under consideration in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 5 the term "prevention" implies a perfect barrier to the effects defined; when in reality this is very unlikely in most cases. Applicant is respectfully requested to either provide convincing evidence of the capability to prevent, or to amend the claims to substitute less stringent terminology; e.g. -- inhibit--, or the like.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pontecorvo et al. (US Patent No. 4,906,638) in view of Nippon Kayaku KK (JP 53040779). Pontecorvo et al. teaches pharmaceutical compositions comprising anti-epileptic drug (i.e. anticonvulsant) and an effective amount of dextromethorphan to potentiate the anticonvulsant activity of the drug (abstract).

Pontecorvo et al. teaches the composition may be introduced as an oral dose in a sold form such as a tablet, pill of capsule (col. 9, lines 3-4).

Pontecorvo et al. teaches that the amount of dextromethorphan used should be at least sufficient to potentiate the anticonvulsants and to lower the minimum effective dose of the anticonvulsant.

Pontecorvo et al. teaches a method of treating epilepsy and other convulsions comprising administration of an effective amount of the composition comprising compositions comprising anti-epileptic drug (i.e. anticonvulsant) and an effective amount of dextromethorphan (see claims 1-9).

Pontecorvo et al. does not teach the specific anticonvulsants, tolperisone or eperisone which correspond to the structure in Applicant claim 1.

Pontecorvo et al. does not teach the compounds present in the composition at specific ranges of Applicant claims 1 and 2.

Pontecorvo et al. does not teach dosage forms contains the specific amount mgs recited in Applicant's claim 3.

Nippon Kayaku KK (JP 53040779) teaches compositions comprising tolperisone have central muscle relaxant, anticonvulsive and anti-asthmatic properties.

Nippon Kayaku KK (JP 53040779) does not teach the composition comprising dextromethorphan.

Accordingly, one of ordinary skill in the art, at the time of Applicant's instant invention, would have a reasonable expectation of success in formulating an composition comprising an anticonvulsant/ muscle relaxant such as tolperisone or eperisone and dextromethorphan and using said composition to treat spasticity and/or pain because Pontecorvo et al teaches pharmaceutical compositions comprising anti-epileptic drugs (i.e. anticonvulsants/muscle relaxants) and dextromethorphan to potentiate the anticonvulsant activity of the drug are useful for treating epilepsy and other convulsions (i.e. spasticity) and Nippon Kayaku KK teaches compositions comprising tolperisone have central muscle relaxant, anticonvulsive and anti-asthmatic properties.

As to the specific amounts of the anticonvulsant and dextromethorphan recited in Applicant's claims 1 and 2 the presence of the two ingredients is taught and it would be obvious to optimize the ranges of both the anticonvulsant and the dextromethorphan. Accordingly, "[W]here the general conditions of a claim are disclosed in the prior art, it is

not inventive to discover the optimum or workable ranges by routine experimentation." *In re* Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

As to the dosage amount present in the dosage unit in Applicant claim 3, it is well within the knowledge of an ordinary artisan to formulate a dosage unit with an appropriate amount of active agent(s).

The idea for combining these references flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423,426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). Additionally, no patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See In re Sussman, 1943 C.D. 518; In re Huellmantel 139 USPQ 496; In re Crockett 126 USPQ 186.

Conclusion

No claims allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JUNE ROGERS whose telephone number is (571)270-3497. The examiner can normally be reached on M-F 9-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fred Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Juné M. Rogers

Frederick Krass
Supervisory Patent Exr
Art Unit 4172